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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,265	11/14/2003	Nadine Ferdman Burton	051438-5002	8062
9629	7590	05/26/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			HILL, LAURA C	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,265

Applicant(s)

BURTON ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>16 February 2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 16 February 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Specifically there is no English translation of FR 1,077,898 or EP 0150666. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'second housing portion 212' and 'first and second end' of fluid conduit in claim 1, the 'first receptacle 284 proximate the first end' in claim 5, and the 'releasable latch' in claim 20 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

1. Claim 1 objected to because of the following informalities: the 'second housing portions that define a cavity' are not disclosed in the specification or the drawings. Claim 1 is also objected to because on page 3, paragraph 0027 of the specification 'housing 202 includes first and second fluid openings 210, 212 for inserting cannula 100 and cylinder 300' while lines 6-7 of claim 1 recites 'first and second housing portions for holding at least a portion of the fluid conduit.' Claim 1 is also objected to because 'actuator' is not disclosed in the specification or the drawings.

Appropriate correction is required

2. Claim 20 objected to because of the following informalities: on page 6, line 7 of the specification the releasable connector is referred to as 'latching tab 246' while in claim 20 the releasable connector is referred to as 'releasable latch'.

Appropriate correction is required for improved claim language consistency.

Claim Interpretation

3. The 'first and second housing portions' of claim 1 are interpreted to include any surfaces on the valve, including or excluding inner and outer walls 216, 218, that define a cavity or unfilled space in the valve housing.
4. The 'actuator' of claim 1 is interpreted to be buttons 206 that collapse fluid passage of conduit 283 as recited in page 2 of the specification.

Claim Rejections - 35 USC § 102

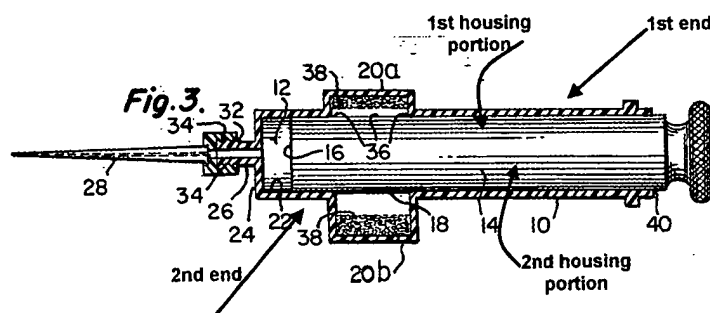
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

5. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Krebs (US 4,065,360). Krebs discloses a culturing syringe device with culturing syringe device, an aspiration cylinder 10, a piston/valve 14, (col. 2, ll. 51-55) comprising:
 - a syringe chamber/removable fluid conduit 12 having a first end for attaching to aspiration cylinder 10 and a second end for attaching to a needle means/cannula 28 (figure 1 and 3);
 - lateral housing walls/valve housing 22 with first and second housing portions (opposite interior and exterior surfaces) that define culturing activities 20 that hold a portion of syringe chamber/removable fluid conduit 12 (col. 2, ll. 62-63, figure 3);
 - means for attaching first housing portion to second housing portion to form a single-piece unit (figure 3);

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a sealing means/actuator 36 that controls fluid flow whenever the piston is in a collapsed position in each of the housing portions of the culturing cavities 20 with respect to the interior of the syringe chamber/removable fluid conduit 12 (and 68- col. 3, line 5, figure 3);



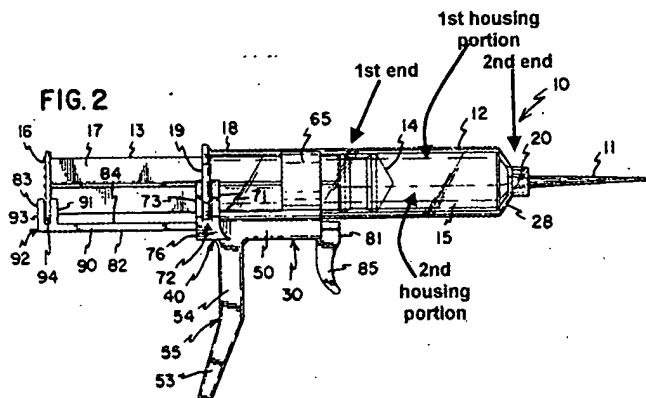
6. Claims 1-3 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 5,115,816). Regarding claims 1-3 Lee discloses a disposable single-piece plastic aspirating device comprising an aspiration cylinder 10 and a syringe barrel/valve 12 (col. 3, ll. 19-21, col. 4, ll. 14-16), comprising:

A plunger /removable fluid conduit 13 having a first end for attaching to the aspiration cylinder 10 and a second end for attaching to needle/cannula 11 (figure 2);

A gasket/valve housing 14 having opposing surfaces/first and second housing portions (opposite interior and exterior surfaces) that define a cavity so interior plunger 13/removable fluid conduit is sealingly received within barrel/valve 12 (col. 4, ll. 32-38 and figure 2);

First and second housing portions capable of having a means for removably attaching since so interior plunger/fluid conduit 13 is removable;

A back wall/actuator 93, coupled to gasket/valve housing 14, that aspirates and directs fluid in a downward path into the barrel (col. 6, ll. 53-56 and figure 2).



Regarding claim 9 Lee discloses first and second housing portions, which engage plunger/removable fluid conduit 13 and are capable of restraining movement of the fluid conduit relative to the housing (figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5,115,816) as applied to claim 1. Lee discloses the plastic aspiration device as

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discussed in rejected claim 1 but does not expressly disclose the plastic comprises polypropylene. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify Lee to include polypropylene since polypropylene is a well-known plastic and since Lee discloses a plastic aspiration device.

8. Claims 5-8, 10-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5,115,816) as applied to claim 1 in view of Imonti (US 5,098,416). Regarding claims 5-8 and 13-14 Lee discloses the plastic aspiration receptacle with fluid conduit and aspiration cylinder as discussed in rejected claim 1. Lee does not expressly disclose a first receptacle, which provides a sealed connection between the fluid conduit and aspiration cylinder. Imonti discloses a medical grade plastic aspiration device 12 with an aspiration cylinder 18, a fluid conduit 14 capable of being removable, a syringe assembly/valve 14 with a first end for attaching to an aspiration cylinder 18 and a second end for attaching to a cannula 34, and a body portion/valve housing 26 (col. 4, ll. 9-15, figure 2). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Imonti further discloses an adapter assembly/first sealing receptacle 10 proximate the first end of fluid conduit 14, which removably couples an aspirator apparatus 12 to a syringe assembly/fluid conduit 14 to form an integrally formed component (col. 3, ll. 18-22, figures 1-2). Imonti does not expressly disclose an actuator. It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the actuator of Lee with the first receptacle

of Imonti to form a resilient silicone integrally formed conduit since both references teach plastic medical aspirator devices for removing fluid via a conduit structure.

Regarding claims 10-12 Lee discloses the aspiration device discussed in rejected claim 1. Lee does not expressly disclose a cap that connects first and second housing portions, extends outwardly from an end of the housing and over the portion of the conduit or that engages fluid conduit to restrain movement of fluid conduit relative to the housing. Imonti discloses luer adapter/cap 42, which extends radially outward from an end of the housing, extends over and away from a portion of the fluid conduit 14, and is received in slot 24 so as to removably couple the first and second housing portions of adapter assembly/first sealing receptacle 10 to the aspirator assembly 12 and provides the coupling means for the adapter assembly 10 (col. 4, ll. 47-54, figure 2). It would be obvious to one of ordinary skill in the art at the time the invention was made to modify Lee to include the cap of Imonti since both references disclose aspiration assemblies for removing body fluid.

Regarding claim 15 Lee discloses the aspiration device with aspiration cylinder 10, valve 12 with housing portions 14 and inner and outer walls, a releasable connector with a cavity, a fluid conduit 13 retained in the cavity, and an actuator 93 for controlling the flow of liquid in the fluid conduit as discussed in rejected claim 1 (figure 2). Lee does not expressly disclose a conduit clamp that acts as an actuator to compress the conduit portion to control the flow of liquid. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify Lee to use a clamp or any other means

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since Lee discloses an aspiration device with an actuating means that compress the conduit portion to control liquid flow.

Regarding claims 16-23 Lee discloses an aspirating device with conduit clamp as discussed in rejected claim 15. Lee does not expressly disclose living hinges or releasable latches for enabling the first housing portion to pivot relative to the second housing portion. Imonti discloses a syringe locking device/hinge 44 that provides a means for releasably coupling the adapter assembly/first sealing receptacle 10 to the syringe assembly/fluid conduit 14 (col. 4, ll. 60-63). Neither reference expressly discloses a pivoting action, the type of hinge used for a pivoting action or latch tab and tab recess components. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the Lee/Imonti references to include a pivoting hinge, latch tab and tab recess components since both references disclose an improved aspirating assembly for controlling and collecting body fluid.

Regarding claim 24 Lee discloses an aspiration device as discussed in rejected claim 15. Lee/Imonti disclose a cap connected to at least one of the first and second ends of the housing as discussed in rejected claims 10-12.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Schweblin reference, US patent no. 4,639,248, is cited for showing a single-piece plastic aspiration device with an aspiration cylinder with variable volume, a valve housing and actuating means.

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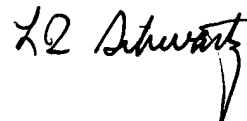
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH



Larry I. Schwartz
Supervisory Patent Examiner
Group 3700

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Commissioner for Patents